



Harmonization of Financial Disclosure in Biomedical Journals: A Shared Responsibility

Recommendations from the Working Groups on Harmonization

July 2020

**Harmonization of Financial Disclosure Reporting in Biomedical Journals:
A Shared Responsibility
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Executive Summary

Safeguarding public trust in biomedical research requires greater consistency in the reporting of financial interests across biomedical journals and the research enterprise as a whole. While the research community has made meaningful strides toward a more unified understanding of how to manage authors' financial interests and activities,¹ many journals still have similar but distinct reporting policies that may be implemented inconsistently. Inconsistent disclosure of information across journals makes it more challenging for authors to report accurately and for readers and audiences to understand the significance of disclosure reports.

The scientific and medical communities share a responsibility for the integrity of biomedical research as well as sharing a commitment to transparency and public trust. Recognizing this shared responsibility, a diverse group of organizations came together to consider whether a path could be found to harmonize financial disclosure standards, principally in connection with journal authorship. A symposium hosted by the Association of American Medical Colleges (AAMC), American Society of Clinical Oncology (ASCO), Council of Medical Specialty Societies (CMSS), JAMA, and Memorial Sloan Kettering Cancer Center in February 2019 yielded a strong consensus view that harmonized disclosure was a worthy goal and would require collaboration among multiple stakeholders. Three working groups were formed and held multiple conference calls over a six-month period to develop the harmonized disclosure framework (HDF) described in this report.

The basis of the HDF is that authors disclose all financial interests in and relationships with healthcare companies, broadly defined, regardless of the nexus between the relationship and the research or subject matter of the authored work. Within this comprehensive disclosure, authors should have the ability to identify which of those relationships are relevant – i.e., directly related – to the authored work. This combination of comprehensive disclosure and designation of relevance minimizes subjectivity and allows readers to make their own judgments as to what disclosure information is pertinent to their understanding of the work.

The HDF calls for authors to disclose relationships that exist at the time a work is accepted for publication and relationships and activities that existed or took place in the immediately preceding two years. The two-year disclosure period represents a time period that yields a meaningful disclosure while presenting a manageable amount of information for journals and readers. The categories for disclosure under the HDF are Financial Stake, Professional Services, Intellectual Property, Financial Support (whether to the author or to the author's institution) and Other Relationships (which may include certain interests held by the disclosers' immediate family members).

Under the HDF, authors are responsible for complete and accurate disclosure of their financial interests and activities. Authors should be given opportunities to correct their disclosures both before and after publication. The HDF does not prescribe a new enforcement mechanism for the failure to completely and accurately disclose. If concerns are raised about the completeness or accuracy of an author's disclosure, journals should follow established standards and procedures set forth by key stakeholder organizations such as the International Committee of Medical Journal Editors (ICMJE) and the Committee on Publication Ethics (COPE) concerning corrections, errata, publication of statements of concern, retractions, and formal apologies for failure to disclose.

¹ Access ICMJE Current Disclosure Form: <http://www.icmje.org/conflicts-of-interest/>; 2019 Proposed Disclosure Form: <http://www.icmje.org/news-and-editorials/proposed-disclosure-form.pdf> (last visited, May 11, 2020).

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Journals are encouraged to adopt the HDF and to implement the HDF as soon as it is feasible to do so in view of their own operations and resources. In addition, other stakeholder organizations across the biomedical research, education, and professional community are encouraged to adopt the HDF in order to promote consistent, transparent disclosure and management of author and faculty interests, and to help guide guideline development.

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The recommendations in this report reflect the views of the Working Group members, and not necessarily those of their organizations. The Working Group Members' affiliations are provided for reference.

The organizations coordinating the initiative “Harmonizing Financial Disclosures in Biomedical Journals” are the **Association of American Medical Colleges, American Society of Clinical Oncology, Council of Medical Specialty Societies, JAMA, and Memorial Sloan Kettering Cancer.**

These Host Organizations appreciate the dedication and expertise of the members of Working Groups on Harmonization and would especially like to thank the co-chairs of each working group for their work. Throughout the initiative, all working groups received substantive input, logistic support, and ongoing guidance from representatives from these five organizations, as co-chairs, designated working group liaisons, or working group activity coordinators.

The Host Organizations would like to specifically note the substantial contributions and insight provided by Pamela Miller, who co-chaired the Working Group on Uniform Disclosure Criteria. Pam’s work at *The New England Journal of Medicine* spanned 20 years and left a lasting impact on the biomedical research community, especially in the areas of disclosure and conflict of interest. Pam passed away on April 29, 2020 just before the completion of this report but was instrumental in the development and products of this initiative.

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Section I. Relevancy of Financial Interests

Comprehensive Disclosure under the Harmonized Disclosure Framework (HDF)

Transparency and consistency in the reporting of authors' financial interests and relationships to biomedical journals serves as a primary foundation of the HDF. In order to ensure the complete and accurate reporting of those interests and relationships, authors should err on the side of "comprehensive disclosure"—the disclosure of *all financial interests and professional relationships* related to medicine, health care, research, and the life sciences regardless of whether those interests are directly related to the article for which the information is being provided.

Assuming the information that is disclosed is up to date and reported accurately and honestly, this approach would help to provide complete transparency with respect to an author's financial interests, decrease the likelihood that financial interests relevant to the article are not disclosed, and mitigate the subjectivity related to an individual author's determination of whether specific financial interests, other interests, and/or relationships should be reported. It would also build and maintain public trust by allowing readers to determine which disclosures are important to the interpretation of the article. As an added benefit, comprehensive disclosure would be applicable to the author's other professional activities. Comprehensive disclosure can be the basis for stakeholders to harmonize disclosures in connection with other scientific and medical activities.

Recommendations - Comprehensive Disclosure of all Financial Interests and Relationships

- Authors should be required to disclose *all interests and relationships* related to medicine, healthcare, research and the life sciences ("comprehensive disclosure"). This also includes the complete disclosure of relationships with and financial interests in organizations or companies whose business includes: research and development, production, marketing, sale, or distribution of healthcare/life sciences products or services (including insurers, technology companies, organizations with healthcare research products or services).
- Authors ordinarily do not report their relationships with organizations that provide clinical services directly to patients or organizations whose primary mission is to educate healthcare professionals (e.g., employment by academic medical centers). If an author has a proprietary interest in such institution(s) (e.g., equity, private partnership involving entities providing clinical services), those relationships should be reported under the HDF.

Designation of Relevant Interests Directly Related to the Article

In addition to requiring the comprehensive disclosure of financial interests and relationships, authors should also designate which, if any, of their reported relationships and other interests they consider relevant to the subject matter of the article. Under this disclosure framework, the burden is on the author to make the relevancy designation because authors are the most knowledgeable about the actual and perceived relationship between the subject matter of the article and their disclosures. Journal editors are unlikely to have the requisite knowledge to determine which disclosures are relevant.

Knowing which of the disclosed interests and relationships the author considers relevant – meaning *directly related* to the topic and subject matter of the article – will assist readers in assessing and interpreting the article. Furthermore, adopting a comprehensive disclosure model with a designation of relevance serves as an important "check" on the author's designations of particular interests as relevant

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since all of an author's potentially related interests will be reported and available to journals and readers.

Recommendations - Designation of Relevant Interests

- Authors should identify a subset of the “comprehensive disclosures” that the author deems *directly related* to the subject matter or content of the article (“designation” of relevant disclosures).
- To guide authors in making relevance designations, journals could consider the Public Health Service (PHS) regulatory definition of relevance (“a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research”)² and the ICMJE’s form description of relevance: “...interests that could influence how [readers] receive and understand [an author’s] work.”
- Journals should consider supplementing definitions of relevance with questions such as:
 - Does the relationship affect the author’s individual financial interest (e.g., could the author’s financial interests increase or decrease depending on their work/research)?
 - Could the financial interests of a commercial entity with which the author has an interest or relationship be affected (positively or negatively) by the author’s work?
 - Does the work report on research that uses a product, technology or service that is owned, manufactured, or sold by the entity in which the author has an interest or relationship? If so, does the work evaluate the product, technology or service?

Potential Challenges and Objections

While the recommendations for comprehensive disclosure with relevance designations would help to ensure consistency and improve transparency around the financial interests and relationships disclosed to biomedical journals, there are a few potential challenges that should be noted. First, if authors’ disclose large numbers of interests and relationships, it may be difficult for readers to separate the true disclosure ‘signal’ from potential ‘noise.’ Nevertheless, the requirement that authors designate a subset of disclosures they deem relevant should help readers identify important interests, relationships and potential conflicts of interest. Second, the recommended disclosure model likely increases the administrative burden for journals in the collection, processing, and publication of the additional disclosure information included in biomedical articles. However, with the technological capabilities of journal submission systems, it is likely that a proposed financial disclosure reporting mechanism could be automated to help alleviate that burden.

² Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Final Rule (42 CFR 50, Subpart F).

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Section II. Uniform Disclosure Criteria and Process

In addition to the requirements for comprehensive disclosure with annotations for relevancy, the HDF is based on biomedical journals' applying a common set of criteria by which authors disclose their financial relationships and activities. Uniform instructions and expectations for author disclosure would remove variation that may impact readers' ability to objectively interpret research findings. In an developing specific definitions and terminology for the HDF, the feasibility, scalability, and impact of the requirements on authors, journals, and other stakeholders was considered.

Disclosure Period for Financial Interests of the Author

A threshold instruction from journals to authors concerns the period of time during which the reported relationships existed and activities took place: the disclosure period. A two-year (24 month) disclosure period is attainable under the HDF and believed to be a reasonable compromise for journals and organizations whose disclosure periods may differ. Notably, this recommendation was developed with careful attention to whether it could be operationalized and sustained within the comprehensive disclosure (with designations for relevancy) framework. There was also significant interest in harmonizing the HDF's disclosure period with standards currently used by journals and other stakeholders.

There are varying benefits associated with different disclosure periods, whether it is a period of twelve, twenty-four, thirty-six months, or longer. Ultimately, what is most meaningful and relevant are those interests that exist at the time the research results are shared or that existed in the immediate time period prior. Relationships that existed three, four, or more years prior to the acceptance of the publication but had been concluded more than two years prior to publication acceptance, would not seem to provide or add meaningful information or context to readers' understanding of the authors' relationships in the context of the submitted work.

Recommendations –Disclosure Period for Financial Interests of the Author

- The comprehensive disclosure of individual financial interests related to medicine, health care, research, and the life sciences with a designation of which disclosures are relevant to the manuscript should include interests that are current, anticipated, and existed *within the two years prior to acceptance* of the submission.
- To allow the capture of additional relevant interests during the disclosure timeframe, a authors should be given the opportunity to update their disclosure information *after* the date of acceptance *but before* publication.

Uniform Disclosure Criteria

Other disclosure criteria concern the nature of the financial interests and activities that should be disclosed. The core concepts that serve as the basis for the HDF were based on several existing resources, including the information and standards currently used by biomedical journals such as the current and proposed revisions to the ICMJE disclosure form as well as the four financial interest disclosure categories developed by the *MedBiquitous Financial Interest Working Group*. The MedBiquitous working group, which consisted of a diverse group of experts in the scientific, academic, medicine, and biomedical journal community, was convened in 2014-2016 to develop nationally agreed upon data specifications for financial interest and disclosure data. The disclosure categories included in the HDF are as follows: 1) Professional Services; 2) Financial Stake; 3) Intellectual Property; and 4) Financial Support.

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Recommendations – Disclosure Criteria

(See Appendix 2, Sample Disclosure Criteria and Related Information)

- The required information regarding a disclosed financial interest and/or relationship should identify and categorize the interest or relationship and include specific information about the disclosed interest or relationship. The information should include the name of the entity and a description or categorization of the nature of the relationship only. Under the HDF this should not include additional details about each interest, such as the monetary value of the interest.

Relationship Categories and Related Information

- **Professional Services** [*employment (secondary or ancillary employment outside of an individual's primary affiliation); fiduciary role; and independent contractor*] Disclosure instructions or guidance related to the Professional Services category should include consulting, speaking, speakers bureaus, advisory boards, and comparable activities.
- **Financial Stake** [*stock; stock option; other securities; other business ownership*] Disclosure instructions or guidance related to the Financial Stake category should emphasize that equity interests, including founders' shares and equity options in start-up companies, even if the value is nominal or unknown, must be disclosed as a financial interest under this category.
- **Intellectual Property (IP)** [*patent or published patent application and copyright, royalties, other licensed IP*] Disclosure instructions or guidance related to the IP category should stipulate that patents, licenses, and similar interests must be disclosed even if they are not yet paying royalties.
- **Financial Support** [*gift; grant/contract; travel; meals*]
 - All sources of individual author support and funding for research should be disclosed in the Financial Support Category.

In cases where research funding comes through the author's institution of employment and the author is carrying out the funded research as part of his/her institutional responsibilities and not personally financially benefitting from the research support to the institution, there may be some confusion related to the disclosure of such support in the context of an individual financial interest disclosure.

However, research support from entities related to medicine, health care, research, and the life sciences could be relevant to an article and/or inform readers of potential biases, even when such sources are not directly supporting the research that is the subject of the submitted work and/or do not involve specific individual financial interests of the author(s).

Any and all direct sources of funding for the research in the submitted work should continue to be separately disclosed in the context of the manuscript.

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- Travel and meals should be disclosed as Financial Support *only when* it is a distinct transaction or relationship not already disclosed in another financial interest category (i.e., solely a travel payment or reimbursement with no associated professional services or disclosure).

The journal disclosure process under the HDF captures relationships with companies, not dollar amounts, and without the need to track each payment, the overall relationship that would result in a sponsored or reimbursed travel disclosure would generally already be captured in the disclosure for the Professional Services category. Although the Centers for Medicare and Medicaid Services' (CMS) Open Payments system does capture this separately, this HDF does not recommend such an approach.

Disclosure of “Other” Financial Interests and Relationships

The disclosure criteria outlined above adequately capture the types of financial interests and relationships critical for stakeholders to be aware of and therefore, the HDF does not require the inclusion of additional financial interest and/or relationship categories.

A separate open-ended question should allow for the capture of *other* additional financial interests or relationships relevant to the submitted work which should include but not be limited to:

- 1) Interests or relationships held by an author's immediate family member(s) if relevant to the submitted work;
- 2) Any other author interests or relationships relevant to the submitted work and not already disclosed.

Recommendations – “Other” Financial Interests and Relationships

- **Financial Interests of Immediate Family Members** - The financial interests and/or relationships of an author's immediate family members should be disclosed by the author *only when* such interests are *relevant (i.e. directly related)* to the article and *should not be disclosed* in the context of the “comprehensive disclosure” requirement. It is sufficient for the author to disclose the immediate family member's relevant relationship in response to the “other interests” question. Journals should reference the Public Health Service definition of “Immediate Family Member” which includes spouse and dependent children.³
- **Institutional Interests** - The position of the HDF is that it is *not feasible* for authors to disclose institutional interests. However, if an author has specific knowledge of any financial or non-financial interest that is directly related to the submitted work (whether individual or institutional) and the author wishes to disclose that interest, the “other interests” question is designed to capture this information.

³ Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Final Rule (42 CFR 50, Subpart F).

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Section III. Principles of Accountability

Author Responsibility for Complete and Accurate Reporting

Under the HDF, disclosure is an author responsibility. Biomedical journals should expect authors to provide a complete and accurate reporting of financial interests and relationships, helping to proactively foster and preserve public trust in the biomedical research enterprise and enabling readers to make individual determinations about whether authors' interests are pertinent to the interpretation of the article. Author disclosure systems should be based on a fundamental presumption of trust and integrity and not designed around "bad actors," those individuals who may not embrace transparency or purposefully omit or falsify data. These principles of responsibility and trust underlie the HDF.

The ICMJE⁴ and COPE⁵ provide guidance to help interested parties identify steps that should be taken to meaningfully address publication and editorial issues such as honest error and the deception or intentional manipulation of data in a submitted or published work. These resources are also useful to journals and stakeholders in addressing issues with author disclosure. Journals and stakeholders should be encouraged to incorporate the HDF's recommendations into their policies and processes, along with relevant guidance from ICMJE, COPE and other organizations, and to communicate these policies and processes to authors and reviewers.

Recommendations – Author Responsibility for Complete and Accurate Reporting

- Every author plays an important role in the preservation of public trust and confidence in the biomedical research enterprise and has a primary responsibility for the complete and accurate reporting of his/her/their financial interests and relationships under the HDF.
- Potential allegations expressing concern regarding disclosure practice by author(s) related to submitted or published work should *not* be labeled as "research misconduct" as defined by the Department of Health and Human Services' Office of Research Integrity. While such allegations should prompt further review by appropriate parties, disclosure is a matter between the author and the journal, separate from the conduct of the research itself.
- Authors should be provided with the opportunity to clarify or correct disclosure errors or omissions *after acceptance* of the article but *before publication*. Corrections should also be permitted *after publication* and if a correction is made, journals should publish a corrective notice with the author's explanation or expression of regret.
- Physicians have limited control over the information reported about them by manufacturers and published on the CMS Open Payments website. Given the requirements of the Open Payments program are set forth in statute (Section 6002 of the Patient Protection and Affordable Care Act), there are limitations on the changes CMS can make without statutory authority.

Open Payments is a U.S. only reporting system and journals and key stakeholders (e.g., academic institutions, professional societies) should view Open Payments as *complimentary* to the HDF. When feasible, journals and key stakeholders should encourage authors to utilize the educational

⁴International Committee of Medical Journal Editors, *International Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* (2009).

⁵COPE, <https://publicationethics.org/> (last visited, May 11, 2020).

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resources and tools provided by CMS and other organizations to help facilitate the Open Payments review, dispute, and data correction process. Because the sources of information and criteria differ between Open Payments and HDF, any discordance between author disclosure under the HDF and the information published on Open Payments should *not* be presumed to be an author's error or intentional omission.

- Editors also carry important responsibilities such as the management of potential or perceived conflicts of interest raised by their own financial interests and relationships related to the article under review. Editors and senior journal staff should furnish their comprehensive disclosure according the HDF and follow their journals' policies as well as guidelines outlined by ICMJE, COPE, and other organizations, to make appropriate editorial judgements (e.g., recusal, publication of disclosure statements).

Corrective Actions – Consequences for Failure to Completely and Accurately Disclose

There may be circumstances where corrective actions are needed to rectify issues such as honest errors, misinterpretations, or purposeful misrepresentation of financial interests or relationships. While the HDF does not provide specific recommendations for author discipline, journals should refer to existing rules and conventions set forth in medical publishing and the continuing medical education community to make a determination on whether an error was intentional and the necessary steps for corrective action.

Recommendations – Consequences for Failing to Completely and Accurately Disclose

- If corrective action is necessary, journals should follow established standards and procedures set forth by key stakeholder organizations such as ICMJE and COPE concerning corrections, errata, publication of statements of concern, retractions, and formal apologies for failure to disclose.⁶
- Egregious cases *may* require journals to communicate the matter to an author's employer or home institution for review and potential corrective action.
- Corrective actions in other contexts, such as continuing professional education, should follow relevant accrediting body standards and practices.

⁶ See, ICMJE *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*, also see COPE *Retraction Guidelines* (2019), <https://publicationethics.org/retraction-guidelines> (last visited, May 11, 2020).

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Section IV. Adoption and Implementation of the Harmonized Disclosure Framework

Adoption of the HDF and Coordinated Communication across Key Stakeholders

Harmonizing disclosure requirements is a challenging undertaking. For the HDF to be successful, there is a need for coordinated communication, shared responsibility, and wide adoption across domestic and international journals.

Consistency and trust would be further enhanced if the HDF was adopted by other organizational entities that require individual reporting of financial interests, activities, and relationships with companies. These other stakeholders may include professional societies, scientific congresses, continuing medical education community, healthcare providers, governmental and non-governmental advisory panels, and grant-making organizations. Use of the HDF by these stakeholders would promote consistency and ease administrative burdens for authors, faculty, and professionals.

Recommendations – Adoption of the HDF and Coordinated Stakeholder Communication

- Wherever possible, the ICMJE member journals should incorporate the recommendations and principles of the HDF into the 2020 revisions to the ICMJE Disclosure Reporting Form and related recommendations, which are currently under revision. Adoption of the key aspects of the HDF could help to build on the ICMJE’s current efforts to improve and streamline the disclosure process.
- Large-scale publishers and journal hosting platforms are encouraged to integrate the HDF into their policies as soon as it is feasible to do so.
- Full author disclosure, including the comprehensive set of relationships and information designated by the author as relevant – should be accessible to all readers of the article.
- While the HDF recommendations are primarily intended for journals, the Harmonization Initiative received substantial feedback that other interested stakeholders should consider incorporating relevant aspects of the HDF into their organization’s disclosure policies and processes. Representatives from each of these other organization types have participated in all aspects of the Harmonization Initiative and provided valuable insights into the discussion and deliberations.
 - **Continuing Medical Education Community:** The ACCME, as a leader in the continuing education community, is encouraged to incorporate the basic elements of the HDF in its updated Standards for Integrity and Independence in Accredited Continuing Education.
 - **Government Departments and Agencies:** U.S. agencies and departments should reference the HDF’s recommendations to inform new or existing policy, regulations, or government activities (e.g., the White House Office of Science and Technology Policy effort to streamline conflict of interest reporting requirements across government agencies).
 - **Research Funding Agencies:** The National Institutes of Health, Food and Drug Administration, and National Science Foundation should accept disclosure reports that utilize the HDF.
 - **Academic Institutions:** To help support the implementation of the HDF, research institutions should be encouraged to incorporate key aspects of the HDF, whether through inclusion in institutional conflict of interest policies or processes or by providing educational opportunities for faculty and staff. Federal and state regulations may require academic institutions to collect information in a different way than what has been recommended under the HDF.

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Considerations for Implementation of the HDF

Implicit in the design of the HDF is the flexibility for journals and other interested stakeholders to make implementation decisions that fit their organizational needs. The HDF has also been designed to permit easy updates or modifications as the disclosure landscape is influenced by new regulations, policies, or disclosure standards.

Recommendations - Considerations for Implementation of the HDF

- Journals and organizations are encouraged to implement the HDF with minimum modification or customization to ensure the recommendations are applied consistently across stakeholders that adopt the HDF. This may require transitioning away from prior disclosure requirements. It is recognized that in some cases, it may be necessary for an organization to require supplemental disclosure of information for specific professional activities or to help manage potential conflicts of interest.
- The ICMJE member journals, as part of the effort to revise the disclosure collection process and form, recently announced several updates to their current disclosure policies, including the acceptance of disclosures from web-based repositories with criteria consistent with ICMJE requirements, and encouraged the development of repositories that meet those qualifications. The decision to accept disclosures from ICMJE qualified web-based systems will help minimize unintentional author disclosure errors or omissions in addition to accommodating regional, linguistic, and regulatory needs. Organizations should have the flexibility to implement the HDF using the technology that is appropriate for their organization.
- Journals, professional societies, and other interested stakeholders should implement the HDF within a reasonable amount of time. This timeframe should be based on the organization's operational needs, resources, and bandwidth.

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Appendix 1

Recommendations

Comprehensive Disclosure of all Financial Interests and Relationships

- Authors should be required to disclose *all interests and relationships* related to medicine, healthcare, research and the life sciences (“comprehensive disclosure”). This also includes the complete disclosure of relationships with and financial interests in organizations or companies whose business includes: research and development, production, marketing, sale, or distribution of healthcare/life sciences products or services (including insurers, technology companies, organizations with healthcare research products or services).
- Authors ordinarily do not report their relationships with organizations that provide clinical services directly to patients or organizations whose primary mission is to educate healthcare professionals (e.g., employment by academic medical centers). If an author has a proprietary interest in such institution(s) (e.g., equity, private partnership involving entities providing clinical services), those relationships should be reported under the HDF.

Designation of Relevant Interests

- Authors should identify a subset of the “comprehensive disclosures” that the author deems *directly related* to the subject matter or content of the article (“designation” of relevant disclosures).
- To guide authors in making relevance designations, journals could consider the Public Health Service (PHS) regulatory definition of relevance (“a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research”)⁷ and the ICMJE’s form description of relevance: “...interests that could influence how [readers] receive and understand [an author’s] work.”
- Journals should consider supplementing definitions of relevance with questions such as:
 - Does the relationship affect the author’s individual financial interest (e.g., could the author’s financial interests increase or decrease depending on their work/research)?
 - Could the financial interests of a commercial entity with which the author has an interest or relationship be affected (positively or negatively) by the author’s work?
 - Does the work report on research that uses a product, technology or service that is owned, manufactured, or sold by the entity in which the author has an interest or relationship? If so, does the work evaluate the product, technology or service?

Disclosure Period for Financial Interests of the Author

- The comprehensive disclosure of individual financial interests related to medicine, health care, research, and the life sciences with a designation of which disclosures are relevant to the manuscript should include interests that are current, anticipated, and existed *within the two years prior to acceptance* of the submission.
- To allow the capture of additional relevant interests during the disclosure timeframe, authors should be given the opportunity to update their disclosure information *after* the date of acceptance *but before* publication.

⁷ Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Final Rule (42 CFR 50, Subpart F).

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Disclosure Criteria

(See Appendix 2, Sample Disclosure Criteria and Related Information)

- The required information regarding a disclosed financial interest and/or relationship should identify and categorize the interest or relationship and include specific information about the disclosed interest or relationship. The information should include the name of the entity and a description or categorization of the nature of the relationship only. Under the HDF this should not include additional details about each interest, such as the monetary value of the interest.

Relationship Categories and Related Information

- **Professional Services** [*employment (secondary or ancillary employment outside of an individual's primary affiliation); fiduciary role; and independent contractor*] Disclosure instructions or guidance related to the Professional Services category should include consulting, speaking, speakers bureaus, advisory boards, and comparable activities.
- **Financial Stake** [*stock; stock option; other securities; other business ownership*] Disclosure instructions or guidance related to the Financial Stake category should emphasize that equity interests, including founders' shares and equity options in start-up companies, even if the value is nominal or unknown, must be disclosed as a financial interest under this category.
- **Intellectual Property (IP)** [*patent or published patent application and copyright, royalties, other licensed IP*] Disclosure instructions or guidance related to the IP category should stipulate that patents, licenses, and similar interests must be disclosed even if they are not yet paying royalties.
- **Financial Support** [*gift; grant/contract; travel; meals*]
 - All sources of individual author support and funding for research should be disclosed in the Financial Support Category.

In cases where research funding comes through the author's institution of employment and the author is carrying out the funded research as part of his/her institutional responsibilities and not personally financially benefitting from the research support to the institution, there may be some confusion related to the disclosure of such support in the context of an individual financial interest disclosure.

However, research support from entities related to medicine, health care, research, and the life sciences could be relevant to an article and/or inform readers of potential biases, even when such sources are not directly supporting the research that is the subject of the submitted work and/or do not involve specific individual financial interests of the author(s).

Any and all direct sources of funding for the research in the submitted work should continue to be separately disclosed in the context of the manuscript.

- Travel and meals should be disclosed as Financial Support *only when* it is a distinct transaction or relationship not already disclosed in another financial interest category (i.e.,

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solely a travel payment or reimbursement with no associated professional services or disclosure).

The journal disclosure process under the HDF captures relationships with companies, not dollar amounts, and without the need to track each payment, the overall relationship that would result in a sponsored or reimbursed travel disclosure would generally already be captured in the disclosure for the Professional Services category. Although the Centers for Medicare and Medicaid Services' (CMS) Open Payments system does capture this separately, this HDF does not recommend such an approach.

“Other” Financial Interests and Relationships

- **Financial Interests of Immediate Family Members** - The financial interests and/or relationships of an author's immediate family members should be disclosed by the author *only when* such interests are *relevant (i.e. directly related)* to the article and *should not be disclosed* in the context of the “comprehensive disclosure” requirement. It is sufficient for the author to disclose the immediate family member's relevant relationship in response to the “other interests” question. Journals should reference the Public Health Service definition of “Immediate Family Member” which includes spouse and dependent children.⁸
- **Institutional Interests** - The position of the HDF is that it is *not feasible* for authors to disclose institutional interests. However, if an author has specific knowledge of any financial or non-financial interest that is directly related to the submitted work (whether individual or institutional) and the author wishes to disclose that interest, the “other interests” question is designed to capture this information.

Author Responsibility for Complete and Accurate Reporting

- Every author plays an important role in the preservation of public trust and confidence in the biomedical research enterprise and has a primary responsibility for the complete and accurate reporting of his/her/their financial interests and relationships under the HDF.
- Potential allegations expressing concern regarding disclosure practice by author(s) related to submitted or published work should *not* be labeled as “research misconduct” as defined by the Department of Health and Human Services' Office of Research Integrity. While such allegations should prompt further review by appropriate parties, disclosure is a matter between the author and the journal, separate from the conduct of the research itself.
- Authors should be provided with the opportunity to clarify or correct disclosure errors or omissions *after acceptance* of the article but *before publication*. Corrections should also be permitted *after publication* and if a correction is made, journals should publish a corrective notice with the author's explanation or expression of regret.
- Physicians have limited control over the information reported about them by manufacturers and published on the CMS Open Payments website. Given the requirements of the Open Payments

⁸ Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Final Rule (42 CFR 50, Subpart F).

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program are set forth in statute (Section 6002 of the Patient Protection and Affordable Care Act), there are limitations on the changes CMS can make without statutory authority.

Open Payments is a U.S. only reporting system and journals and key stakeholders (e.g., academic institutions, professional societies) should view Open Payments as *complimentary* to the HDF. When feasible, journals and key stakeholders should encourage authors to utilize the educational resources and tools provided by CMS and other organizations to help facilitate the Open Payments review, dispute, and data correction process. Because the sources of information and criteria differ between Open Payments and HDF, any discordance between author disclosure under the HDF and the information published on Open Payments should *not* be presumed to be an author's error or intentional omission.

- Editors also carry important responsibilities such as the management of potential or perceived conflicts of interest raised by their own financial interests and relationships related to the article under review. Editors and senior journal staff should furnish their comprehensive disclosure according the HDF and follow their journals' policies as well as guidelines outlined by ICMJE, COPE, and other organizations, to make appropriate editorial judgements (e.g., recusal, publication of disclosure statements).

Consequences for Failing to Completely and Accurately Disclose

- If corrective action is necessary, journals should follow established standards and procedures set forth by key stakeholder organizations such as ICMJE and COPE concerning corrections, errata, publication of statements of concern, retractions, and formal apologies for failure to disclose.⁹
- Egregious cases *may* require journals to communicate the matter to an author's employer or home institution for review and potential corrective action.
- Corrective actions in other contexts, such as continuing professional education, should follow relevant accrediting body standards and practices.

Adoption of the HDF and Coordinated Stakeholder Communication

- Wherever possible, the ICMJE member journals should incorporate the recommendations and principles of the HDF into the 2020 revisions to the ICMJE Disclosure Reporting Form and related recommendations, which are currently under revision. Adoption of the key aspects of the HDF could help to build on the ICMJE's current efforts to improve and streamline the disclosure process.
- Large-scale publishers and journal hosting platforms are encouraged to integrate the HDF into their polices as soon as it is feasible to do so.
- Full author disclosure, including the comprehensive set of relationships and information designated by the author as relevant – should be accessible to all readers of the article.
- While the HDF recommendations are primarily intended for journals, the Harmonization Initiative received substantial feedback that other interested stakeholders should consider incorporating relevant aspects of the HDF into their organization's disclosure policies and processes. Representatives from each of these other organization types have participated in all

⁹ See, ICMJE *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*, also see COPE *Retraction Guidelines* (2019), <https://publicationethics.org/retraction-guidelines> (last visited, May 11, 2020).

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aspects of the Harmonization Initiative and provided valuable insights into the discussion and deliberations.

- ***Continuing Medical Education Community:*** The ACCME, as a leader in the continuing education community, is encouraged to incorporate the basic elements of the HDF in its updated Standards for Integrity and Independence in Accredited Continuing Education.
- ***Government Departments and Agencies:*** U.S. agencies and departments should reference the HDF's recommendations to inform new or existing policy, regulations, or government activities (e.g., the White House Office of Science and Technology Policy effort to streamline conflict of interest reporting requirements across government agencies).
- ***Research Funding Agencies:*** The National Institutes of Health, Food and Drug Administration, and National Science Foundation should accept disclosure reports that utilize the HDF.
- ***Academic Institutions:*** To help support the implementation of the HDF, research institutions should be encouraged to incorporate key aspects of the HDF, whether through inclusion in institutional conflict of interest policies or processes or by providing educational opportunities for faculty and staff. Federal and state regulations may require academic institutions to collect information in a different way than what has been recommended under the HDF.

Considerations for Implementation of the HDF

- Journals and organizations are encouraged to implement the HDF with minimum modification or customization to ensure the recommendations are applied consistently across stakeholders that adopt the HDF. This may require transitioning away from prior disclosure requirements. It is recognized that in some cases, it may be necessary for an organization to require supplemental disclosure of information for specific professional activities or to help manage potential conflicts of interest.
- The ICMJE member journals, as part of the effort to revise the disclosure collection process and form, recently announced several updates to their current disclosure policies, including the acceptance of disclosures from web-based repositories with criteria consistent with ICMJE requirements, and encouraged the development of repositories that meet those qualifications. The decision to accept disclosures from ICMJE qualified web-based systems will help minimize unintentional author disclosure errors or omissions in addition to accommodating regional, linguistic, and regulatory needs. Organizations should have the flexibility to implement the HDF using the technology that is appropriate for their organization.
- Journals, professional societies, and other interested stakeholders should implement the HDF within a reasonable amount of time. This timeframe should be based on the organization's operational needs, resources, and bandwidth.

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Appendix 2

Uniform Disclosure Criteria and Related Information

PROFESSIONAL SERVICES	
Relationship Type Categorization	Information Required
Employment (secondary or ancillary employment outside of one's primary affiliation)	- Entity Name - Title
Fiduciary Role	- Entity Name - Title/Role
Independent Contractor	- Entity Name - Category of Service Provided <ul style="list-style-type: none"> o Consultant/Speaker o Data and Safety Monitoring o End Point Review Committee o Expert Witness o Other
FINANCIAL STAKE	
Relationship Type Categorization	Information Required
Stock	- Entity
Stock Option	- Entity
Other Securities	- Entity
Other Business Ownership	- Entity - Description
INTELLECTUAL PROPERTY	
Relationship Type Categorization	Information Required
Patent or Published Patent Application	- Description - Patent Status - Patent Holder/Owner - Licensee, if applicable
Copyright, Royalties, Other Licensed Intellectual Property	- Description - IP Holder/Owner - Licensee (if applicable)
FINANCIAL SUPPORT	
Relationship Type Categorization	Information Required
Gift	- Entity Name
Grant/Contract	- Entity Name - Purpose/Type of Support

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